Real-Time Data Capture: Review Issues

MICHAEL MICKLIN, Ph.D.
Chief, RPHB IRG
Center for Scientific Review
National Institutes of Health

Preparing the Application: General Guidelines

- **Read instructions (in newest version of PHS 398)**
- **Never assume that reviewers "will know what you mean"**
- **Provide appropriate reasoning for and description of research design, including:**
  - **Participant selection**
  - **Data collection**
  - **Data management**
  - **Data analysis**
  - **Data interpretation**
- **Anticipate human subjects issues**

*EMA Design Issues and Reporting Guidelines**

- **Sampling**
- **Momentary Procedures**
- **Data Acquisition Interface**
- **Compliance**
- **Participant Training and Monitoring**
- **Data Management Procedures**
- **Data Analysis**

***A.A. Stone and S. Shiffman (2002), "Capturing Momentary, Self-Report Data: A Proposal for Reporting Guidelines." *Annals of Behavioral Medicine* 24 (3), Table 1, p. 238.**

Potential Reviewer Issues with EMA-based Applications

- **Research Design**
  - **Does it work? Preliminary data useful**
    - **Pre-test of instrument(s)**
    - **Pilot study of design & expected results**
    - **Is subject training effective?**
    - **Is subject burden manageable?**
    - **Will compliance rate(s) be adequate?**
- **Human Subjects**
  - **Inclusion**
  - **Protection**

Research Involving Human Subjects

Important Considerations

- Is the proposed study exempt from human subject review?
- Are there any apparent risks* to the human subjects?
- Are the protections adequate?
- What are the potential benefits to the subjects and to humankind?
- Are the inclusions of minorities, both genders, and children addressed adequately?

*"Risks" include the possibility of physical, psychological, or social injury resulting from research.

Human Subjects Inclusion and Protection Issues

- **Recruitment and informed consent**
  - **Vulnerable populations:**
    - **Children**
    - **Elderly**
    - **Impaired**
    - **Institutionalized**
  - **Incentives**
  - **Informed consent**
    - **Participation**
    - **Use of information**
- **Data Safety and Monitoring Plan**